



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

AngioDynamics Inc.
c/o Ms. Teri Juckett
603 Queensbury Ave
Queensbury, NY 12804

NOV 26 2010

Re: K100199

Trade/Device Name: AngioDynamics Percutaneous Introducer and VenCureEVL
Procedure Kit
Regulation Number: 21 CFR 878.4810
Regulation Name: Powered Laser Surgical Instrument
Regulatory Class: Class II
Product Code: GEX
Dated: November 8, 2010
Received: November 10, 2010

Dear Ms. Juckett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

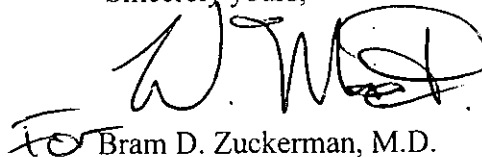
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is stylized with a large initial "B" and a long horizontal stroke.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

K100199
NOV 26 2010

510(k) Application: Traditional 510(k): Device Modification

Device Name: AngioDynamics, Inc. Percutaneous Introducer and VenaCureEVLT Procedure Kit

Indications for Use:

The AngioDynamics, Inc. VenaCureEVLT Procedure Kit with Percutaneous Introducer is indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

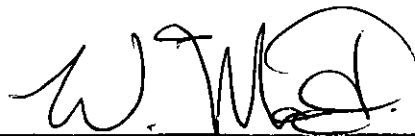
The AngioDynamics, Inc. VenaCureEVLT Procedure Kit is indicated for use with 810 nm and 980 nm Diode Lasers with SMA 905 connectors.

Prescription Use X
(Per 21 CFR 801.109)

OR **Over-the-Counter Use**

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100199

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